REMARKS/ARGUMENTS

In response to the Office Action mailed February 25, 2004, Applicants amend their application and request reconsideration in view of the amendments. In this amendment Claim 1 is amended, Claims 2 and 6-22 were previously cancelled without prejudice and no claims have been added so that claims 1 and 3-5 are currently pending. No new matter has been introduced.

Claims 1 and 3-5 were rejected as anticipated by U.S. Patent Number 6,193,745 to Fogarty et al. (Fogarty). This rejection is respectfully traversed.

The present invention provides modular intraluminal tubular prostheses, particularly stents and stent-grafts, for the treatment of disease conditions, particularly aneurysms. Modular sections of the prostheses, or "prosthetic modules," may be selectively combined to form a composite prosthesis having characteristics which are tailored to the specific requirements of the patient. Each prosthetic module preferably includes one or more standard interface ends for engaging another module, the module/module interface typically comprising ends which overlap and/or lock within a predetermined axial range. Advantageously, the axial length, cross-section, perimeter, resilient expansive force, axial flexibility, liner permeability, liner extensibility, radial conformability, liner/tubal wall sealing and anchoring, and other prosthetic characteristics may be varied along the axis of the composite prosthesis, and also along the axis of each prosthetic module. The modules are preferably individually introduced into a lumen system of a patient body so that the composite prosthesis is assembled in situ. Ideally, selection of appropriate prosthetic modules and the flexibility of the interface overlap range provides a custom fit intraluminal prosthesis which provides a therapy tailored to the individual patient's needs.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is <u>one difference</u> between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent claim 1, is directed to a stent. The stent comprises a plurality of hoops having a plurality of interconnected struts forming a substantially diamond shape configuration, a plurality of sinusoidal rings connecting adjacent hoops to one another, and proximal and distal attachment devices for securing a graft member to the stent. The stent has proximal and distal end hoops that are configured to have greater radial and longitudinal strength than the hoops therebetween. The proximal hoop is flared. The sinusoidal rings being formed from a plurality of alternating struts, wherein a junction of the alternating struts of the sinusoidal rings and a junction of interconnected struts of the plurality of hoops are a common junction. The proximal attachment device is positioned distal of the proximal open-end of the stent such that the proximal open end of the stent is exposed to the body vessel. Both the proximal and distal attachment devices comprise tabs formed from the joining of two struts and have at least two apertures therein. The alternating struts forming the sinusoidal rings are substantially shorter in length than the plurality of interconnected struts of the plurality of hoops.

Fogarty fails to disclose or suggest a separate set of alternating struts substantially shorter than the struts forming the hoops. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 3-5 were rejected as being unpatentable over U.S. Patent Number 6,547,814 to Edwin et al. (Edwin) in view of U.S. Patent Number 5,824,040 to Cox et al. (Cox). Claims 1 and 3-5 were rejected as being unpatentable over U.S. Patent Number 6,270,524 to Kim in view of U.S. Patent Number 6,579,314 to Lombardi et al. (Lombardi). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation,

> either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Edwin discloses a method for selectively bonding layers of polymeric material, especially expanded polytetrafluoroethylene (ePTFE), to create endoluminal vascular devices. In a preferred method the selective bonding is achieved by applying pressure to selected areas using a textured mandrel. This permits a stent device to be encapsulated between two layers of ePTFE with unbonded slip pockets to accommodate movement of the structural members of the stent. This allows stent compression with minimal force and promotes a low profile of the compressed device. Unbonded regions of ePTFE allow

enhanced cellular penetration for rapid healing and can also contain bioactive substance that will diffuse through the ePTFE to treat the vessel wall.

Cox provides a branching endoluminal prosthesis for use in branching body lumen systems which includes a trunk lumen and first and second branch lumens. The prostheses comprises a radially expandable tubular trunk portion having a prosthetic trunk lumen, and radially expandable tubular first and second branch portions with first and second prosthetic branch lumens, respectively. A radially expandable tubular Y-connector portion provides fluid communication between the prosthetic trunk lumen and the first and second prosthetic branch lumens. Although it is often considered desirable to maximize the column strength of endoluminal prostheses, and although the trunk portion will generally have a larger cross-section than much of the remainder of a branching endoluminal prostheses, the expanded trunk portion is more axially flexible than the expanded Y-connector portion, as insufficient flexibility along the trunk portion may result in leakage between the prosthesis and the trunk lumen of the body lumen system. In contrast, the Y-connector portion benefits form a less axially flexible structure to avoid distortion of the flow balance between the luminal branches.

Kim provides methods and apparatus for deploying luminal prostheses, such as stents, grafts, or stent-grafts, to luminal walls at a target site within an anatomical lumen. In one aspect of the invention, luminal prostheses are designed to negotiate curves, bends and other irregularities in body passageways so as to facilitate deployment of the stents and to minimize injury to the luminal walls. In addition, the luminal prostheses of the present invention have sufficient flexibility to bend and articulate so as to substantially conform to a tortuous body lumen at the target site, which enhances the post-deployment performance of the stent. In another aspect of the invention, methods and apparatus are provided for securing luminal prostheses to the luminal walls at a target site within an anatomical lumen. These methods and apparatus provide an effective frictional lock between the stent and the luminal wall to inhibit migration and/or failure of the stent.

Lombardi discloses a portion of a covered stent is encapsulated with ePTFE, so that the unencapsulated portion, which is covered by a single ePTFE covering, imparts an unimpaired flexibility to the stent. One surface of the stent, either the luminal or abluminal surface, is covered by a single continuous layer of ePTFE, while limited regions, preferably near the ends of the stent, of the other surface are also covered by ePTFE. The regions covered by ePTFE on both surfaces become encapsulated when the ePTFE of one layer becomes bonded to second layer. By leaving a middle region of the stent unencapsulated, the stent retains flexibility similar to a bare stent, thereby reducing the loading and deployment forces.

Applicants respectfully submit that the prior art references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations. The references fail to disclose a stent having a plurality of hoops in a diamond configuration, the proximal hoop is flared, a plurality of sinusoidal rings between the hoops and the alternating struts of the sinusoidal rings are substantially shorter than the struts forming the plurality of hoops, and a distal and proximal attachment means formed as tabs at the junctions of struts, wherein the tabs have at least two apertures. In addition, the proximal end hoop is uncovered by graft material.

A favorable Action is respectfully requested.

Respectfully submitted,

By:_____

Carl J. Evens
Reg. No. 33,874

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518
Dated: May 18, 2004